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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,809	10/30/2000	Jeff L. DeJong	119941-1083	3391

7590 03/10/2004

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/703,809	Applicant(s) DEJONG, JEFF L.	
	Examiner Richard G Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 86-107 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 86-88,90,91,93-99,101,102 and 104-107 is/are rejected.
- 7) ☒ Claim(s) 89,100,103 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Applicants amendments the specification and claims 86, 90, 92-97, 103-107 in the papers of 1/15/2004 and 2/20/2004, are acknowledged. Claims 86-107 are still at issue and are present for examination.

Applicants' arguments filed on 1/15/2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/15/2004 has been entered.

Claim Objections

Claims 89, 93, 100, 103 and 104 is objected to because of the following informalities: Claim 104 recites "comprising a portion of the an isolated protein having greater than 90% sequence identity with SEQ ID NO.: 4...". It is suggested that this be

amended to "comprising a portion of **[the]** an isolated protein having greater than **[t]n** 90% sequence identity with SEQ ID NO.: 4...".

Claim 93 recites "greater than 90% sequence". It is suggested that this be amended to "greater than 90% sequence"

Claims 89 and 100 depend on rejected claims 86 and 97, respectively.

Claim 103 recites "comprising a nucleic acid sequence set forth in SEQ ID NO.:4". It is suggested that this be amended to "comprising **the** nucleic acid sequence set forth in SEQ ID NO.:4"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 107 is indefinite in that it is unclear in the recitation "said protein is a transcription factor", as claim 104 from which claim 107 depends, recites three different "proteins" (i.e. "A fusion protein comprising...", "an isolated protein" and "a fusion protein sequence"). Thus it is unclear to which protein applicants are referring in claim 107.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86-88, 90, 91, 93-99, 101, 102, and 104-107 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action as it applied to claims 86-88, 90-99 and 101-107. In response to this rejection applicants have amended claims 86, 90, 92-97 and 103-107 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse on the basis that the claims have been amended in light of the Written Description Guidelines, specifically as they relate to Protein Variants and the amount of disclosure needed to support claims to variants that is, within certain levels of identity, e.g., 90, 95 or 98 percent. Applicants further point out specific support in the specification for various of the encompassed species. Based on the above applicants submit that the guidelines are satisfied as to the level of variation that is known in the art and thus the scope of the claims are based on the numerous known structural features of transcription factors.

Applicants argument is not found persuasive for the reasons previously stated. Applicant is further reminded that the claims are not currently limited merely to

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transcription factors, but rather any protein having the claimed structural relationship to the disclosed SEQ ID NOs. Thus as the specification only provides the representative species of proteins having the amino acid sequence of SEQ ID NO: 2 and 4, there is no disclosure of any particular structure to function/activity relationship in the claimed genus.

The genus of proteins that are claimed is a large variable genus with potentiality of comprising many functionally different proteins. Therefore, many functionally unrelated proteins are encompassed within the scope of these claims. The specification discloses only species of each claimed genus (i.e. having the amino acid sequence SEQ ID NO: 2 and 4) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 86-88, 90, 91, 93-99, 101, 102, and 104-107 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein having the amino acid sequence of SEQ ID NO: 2 or 4, does not reasonably provide enablement for any protein comprising an amino acid sequence of merely having greater than 90% amino acid sequence identity to SEQ ID NOs: 2 or 4.

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The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applied to claims 86-88, 90-99 and 101-107. In response to this rejection applicants have amended claims 86, 90, 92-97 and 103-107 and traverse the rejection as it applies to the newly amended claims.

Applicants do not appear to specifically traverse this rejection beyond applicants traversal of the above rejection based on a lack of written description.

Applicants argument is not found persuasive for the reasons stated above. As above, applicant is reminded that the claims are not currently limited merely to transcription factors, but rather any protein having the claimed structural relationship to the disclosed SEQ ID NOs. Thus as the specification only provides the representative species of proteins having the amino acid sequence of SEQ ID NO: 2 and 4, there is no disclosure of any particular structure to function/activity relationship in the claimed genus and the scope of those proteins remains large with regard to the extremely large number of proteins and fusion proteins broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the

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ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the teachings of those proteins having the amino acid sequence of SEQ ID NO: 2 and 4.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and **use** the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any protein having 90% identity to the amino acid sequence of SEQ ID NO: 2 or 4.. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those proteins having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 104-107 are rejected under 35 U.S.C. 102(b)as anticipated by Ma et al. (Genes and Development 7(11):2246-2257, Nov 1993).

The rejection is stated in the previous office action as it applied to claims 93-96 and 104-107. In response to this rejection applicants have amended claims 86, 90, 92-97 and 103-107 and traverse the rejection as it applies to the newly amended claims.

As stated in the previous office action, Ma et al. teach the cloning and identification of a cDNA clone encoding the largest subunit of TFIIA. The cDNA taught by Ma et al. has a best local similarity score of 66.3 % with nucleotides 3379 to 3663 of SEQ ID NO: 3 and Ma et al. the purification of the TFIIA protein by nickel and TBP chromatography. As a single amino acid constitutes a portion of a TFIIA α / β -like factor protein, Ma et al. teach a fusion protein comprising a portion of a TFIIA α / β -like factor protein and a non-TFIIA α / β -like factor protein sequence.

Applicants traverse this rejection on the basis that applicants claims are not directed to a single amino acid, but rather, a protein having a particular novel amino acid sequence.

Applicants traversal is not found persuasive because applicants are reminded that claim 104 currently is drawn to "an isolated protein comprising **a portion** of the an isolated protein having greater than 90% sequence identity with SEQ ID NO.: 4 and a fusion protein sequence. As previously stated, acknowledged by applicants and repeated again above, a portion of a protein constitutes a single amino acid. Thus, Ma et al. teach a fusion protein comprising a portion of a protein having greater than 90% sequence identity with SEQ ID NO: 4 and a non-TFIIA α / β -like factor protein sequence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
3/5/2004